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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,739	11/16/2000	Hongkui Jin	GENENT.68A2D1	7262

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	4

DATE MAILED: 11/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,739	JIN ET AL.	
	Examiner	Art Unit	
	Robert Landsman	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/16/00* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-59* is/are pending in the application.

4a) Of the above claim(s) *29-48 and 56-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-55* is/are rejected.

7)☒ Claim(s) *53-55* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Formal Matters

A. Preliminary Amendment A, filed 11/16/00, has been entered into the record. Claims 1-28 were pending in the application. However, these claims were cancelled by this amendment and new claims 29-59 were added.

B. The Information Disclosure Statement, filed 1/30/01, has been entered into the record.

2. Election/Restriction

A. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 29-48 and 56-59, drawn to a method for treating cardiac hypertrophy, classified in class 514, subclass 2.

II. Claims 49-52, drawn to a method for making a pharmaceutical composition, classified in class 514, subclass 2.

III. Claims 53-55, drawn to a pharmaceutical product comprising an effective amount of interferon gamma, classified in class 530, subclass 350.

B. The inventions are distinct, each from each other because of the following reasons:

Inventions I and II, III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product, or (2) the product as claimed can be used in a materially different process of using that product MPEP § 806.05(h). In the instant case the pharmaceutical product can be used as antigen for antibody production, or the pharmaceutical composition can be used for methods other than that of treating cardiac hypertrophy.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

C. A telephone call was made to Ginger Dreger on April, 03, 2002 to request an oral election to the above restriction. Applicant's election of Group III, claims 53-55 is acknowledged with traverse. However, upon further consideration, the Examiner has decided to examine Groups II and III together. Therefore, Groups II and III, claims 49-55, will be examined. This restriction is still subject to traversal.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR § 1.48(b) and by the fee required under 37 CFR § 1.17 (h).

3. Claim Objections

A. Claim 53 is objected to since it depends from non-elected claim 29. Claims 54 and 55 are also objected to since they depend from claim 53.

4. Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Pharmaceutical compositions comprising IFN-γ.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 53-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 53 is confusing since it recites "at least one therapeutically effective dosage." However, it is not understood how a container comprising a pharmaceutical composition of IFN-γ can comprise more than one dosage of IFN-γ. Claims 54 and 55 are also rejected since they depend from claim 53.

6. Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 49, 50 and 52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure on page 15, lines 27-30, of Applicants' specification which teaches that a commercial liquid formulation of sterile IFN-γ in a single dose vial for subcutaneous injection was known at the time of the present invention (Actimmune rhuIFN-γ-1b, Genentech, Inc.). This formulation meets all the limitations of claims 53-55 since the recitation of treatment of cardiac hypertrophy is only an intended use of the composition. Furthermore, one of ordinary skill in the art would have immediately envisioned at the time of the present invention that the sterile formulation would have had to have been made using the method of claims 49, 50 and 52, which simply requires combining IFN-γ with a pharmaceutically acceptable carrier.

7. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over page 15, lines 27-30 of the present specification in view of Lam et al. (Pharm. Res. 14(6):725-729, 199). The teachings of the specification are recited in the above rejection under 35 USC 102. The specification does not teach that the composition comprises a preservative. However, Lam et al. do teach the use of the preservative, benzyl alcohol, at 0.9% (w/v) in various liquid IFN-γ formulations. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the present invention to have included a preservative such as benzyl alcohol, in a liquid formulation in order to inhibit microbial growth in the sterile formulation since this product was intended to be used as an injection to treat patients. One of ordinary skill in the art would have had a reasonable expectation of success in producing this formulation since the use of antimicrobial agents such as benzyl alcohol were well-known and widely used at the time of the present invention.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
November 01, 2002